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July 2, 2003

ATTORNEY FOR APPLICANT

7/2/03

DATE

Attorney Docket No. P50965

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gowen, et al.	July 2, 2003	
Serial No.:	10/049,348	Group Art Unit No.:	1617
Filed:	January 30, 2002	Examiner:	T. J. Criares
For:	Calcilytic Compounds		

Commissioner for Patents
Mail Stop: Non-Fee Amendments
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

The following response is provided to the restriction requirement dated March 21, 2003, setting a thirty (30) day shortened statutory period for reply.

The Examiner has divided this application into two (2) groups, as follows:
Group I - claims 1-7, drawn to a method of treating a disease or disorder characterized by an abnormal bone or mineral homeostasis comprising administering an effective amount of a calcilytic compound in conjunction with an effective amount of an anti-resorptive agent; and.
Group II -claims 1-7, drawn to a method of treating a disease or disorder characterized by an abnormal bone or mineral homeostasis comprising administering an effective amount of a anabolic compound in conjunction with an effective amount of an anti-resorptive agent; and.

Applicants respectfully traverse the above restriction requirement, but provisionally elect Group I for further consideration.

Applicants respectfully traverse the above restriction requirement, but provisionally elect Group 1 for the initial search and examination in accordance with the provisions of MPEP § 803.02.

Applicants elect species N-[(2R-Hydroxy-3-[(3-chloro-2-cyano)phenoxy-propyl]-1,1-dimethyl-2-(2-naphthyl)ethyl amine hydrochloride; as cited in Claim 2 on page 21, lines 9 and 10 in the specification as required by the Examiner.

Applicants traverse the present restriction requirement because (i) the present application was filed under the provisions of 35 U.S.C. § 371, and the present restriction requirement is not in accordance with the unity of invention standard set forth by the PCT, and (ii) it reflects a misapplication of the guidelines of the MPEP and the PCT.

PCT Rule 13.2 states that unity of invention shall be fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art". In the present invention, contrary to the assertions of the Examiner, the technical relationship is provided because the invention in question involves calcilytic compounds mediates diseases and their treatment using the present compounds.

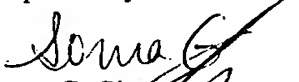
Furthermore, PCT Rule 13.1 includes within the definition of unity of invention "a group of inventions so linked as to form a general inventive concept". Accordingly, patentably distinct inventions do not lack unity of invention as long as they derive from the same inventive concept. What is required for a holding of lack of unity is that the inventions be truly "independent". This is the standard for lack of unity applied by the court in *In re Harnish*, 206 USPQ 300, 306 (CCPA 1980) ("unity of invention" ... appl[ies] where *unrelated* inventions are involved") (emphasis supplied). Independent, as defined in MPEP § 802.01, "means that there is no disclosed relationships between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect".

In the instant case, all of the compounds of the remaining claims share: (i) a common design, as represented by the generic core structure (I), (ii) a common operation as found by their mechanism of action (calcilytic compounds), and (iii) a common effect (treatment of diseases outlined in the specification).

Furthermore, while applicants do not contend that the compounds of the remaining claims are not patentably distinct, the present compounds are so connected as to have arisen from a singular research effort. Accordingly, claim 1 and the other remaining claims read upon a plurality of distinct, but related inventions and fully comply with the unity of invention requirement according to the PCT. They cannot, therefore, be further subdivided or restricted and must be included in a single application.

It is also noted that a restriction requirement under 35 U.S.C. §121 is fully discretionary on the part of the Examiner. Applicants respectfully request that the Examiner exercise her discretion, and withdraw the restriction requirement both with respect to Groups I and II.

Respectfully submitted,



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